# PATENT COOPERATION TREATY



## **PCT**

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

| (Ch  | napter II of the Patern Coopera   |  |  |  |                            |                                       |  |
|--|---|--|--|--|----------------------------|---------------------------------------|--|
|  | (PCT Article 36 and Rul   | le 70)   |  |  |                            |                                       |  |
| pplicant's or agent's file reference   | FOR FURTHER ACTION  | See Form PCT/IPEA/416                                      |  |  |                            |                                       |  |
| 041381CP   |   | h/year) Priority date (day/month/year)                     |  |  |                            |                                       |  |
| ternational application No.  | International filing date (day/mont)<br>20. Sep. 2004 (20. 09.  | 19. Sep. 2003 (19. 09. 2003)                               |  |  |                            |                                       |  |
| PCT/CN2004/001070  | 20. Sep. 2004 (20. de)  |  |  |  |                            |                                       |  |
| PCT/CN2004/001070 International Patent Classification (IPC) or   | national classification and in or   | P15/02, A61P15/08, A61P15/12, A61P19/10                    |  |  |                            |                                       |  |
| C07H15/18, A61K31/70, A61K31/702   | 8, A01823/10,500  |  |  |  |                            |                                       |  |
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| Applicant  | 1 Trachmology Co. Ltd. 6  | et al.   |  |  |                            |                                       |  |
| Shanghai YAO GANG B  | Siological Technology Co. Ltd. e  | shed by this International Preliminary Examining Authority |  |  |                            |                                       |  |
|  | iminary examination report, establish   | 36.  |  |  |                            |                                       |  |
| Applicant Shanghai YAO GANG Biological Technology Co. Ltd. et al.  1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.  Sheets, including this cover sheet.   |   |  |  |  |                            |                                       |  |
| opt consists of a total o  | of 4  |  |  |  |                            |                                       |  |
| This report is also accompanied by   | y ANNEXES, comprising   | sheets, as follows:  |  |  |                            |                                       |  |
| this have been amended and at the 607 of the Administrative  |   |  |  |  |                            |                                       |  |
| a. (sent to the applicant  | ption, claims and/or drawings which   | hority (see Rule 70.16 and Section 55                      |  |  |                            |                                       |  |
| sheets containing re   | contractions are  | Authority considers contain an amendment that goes beyon   |  |  |                            |                                       |  |
| sheets which supersede earlier sheets, but which this Authority considers and of Box No. I and the supplemental sheets which supersede earlier sheets, but which this Authority considers and the Supplemental Sheets which supersede earlier sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets, but which this Authority considers and item 4 of Box No. I and the supplemental sheets are sheets, but which the supplemental sheets are sheets and the supplemental sheets are sheets.  |   |  |  |  |                            |                                       |  |
|  |   |  |  |  | b. [] (sent to the Interna | listing and/or tables related thereto | o, in electronic forms and in instructions). |
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| to the state of th | ns relating to the following items:   |  |  |  |                            |                                       |  |
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| Box 110.1  |   |  |  |  |                            |                                       |  |
| Box No. II Priority  | stablishment of opinion with regard   | to novelty, inventor of                                    |  |  |                            |                                       |  |
| to the of invention  |   |  |  |  |                            |                                       |  |
| Box No. IV Lack C  | ed statement under Article 35(2) wi   | ith regard to novels,                                      |  |  |                            |                                       |  |
| Box No. V Reasoned statement dider to citations and explanations supporting such statement   |   |  |  |  |                            |                                       |  |
| 1  | - documents cited   |  |  |  |                            |                                       |  |
| I DOVINGE  | the international applic  | cation   |  |  |                            |                                       |  |
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| Date of submission of the demar  | id 04 2005)   | 09. Nov. 2005 (09. 11. 2005)                               |  |  |                            |                                       |  |
| 11. April. 200   | 5 (11.04: 2000)   | Authorized officer / Xigo Peng                             |  |  |                            |                                       |  |
| Name and mailing address of the  | e IPEA/CN   |  |  |  |                            |                                       |  |
| The State Intellectual Pro   | perty Office, the P.R.China,<br>perty Office, the P.R.China,<br>ge, Haidian District, Beijing, China<br>20088 |  |  |  |                            |                                       |  |
| 6 Xitucheng Rd., Jimen Bridge  | 00088   | Telephone No. 86-10-62085625=1                             |  |  |                            |                                       |  |
| Facsimile No. 86-10-620194   | 51  | <u> </u>   |  |  |                            |                                       |  |
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International application No. PCT/CN2004/001070

| Box | No.   | o. I Basis of the report   |   |  |  |  |
|-----|---|--|---|--|--|--|
| 1.  | With  | th regard to the language, this report is based on:  |   |  |  |  |
| ۰   | the international application in the language in which it was filed |  |   |  |  |  |
|     |   | a translation of the international application into  | , which is the language of a                                |  |  |  |
|     |   | translation furnished for the purposes of:   |   |  |  |  |
|     | international search (Rules 12.3(a) and 23.1(b))                    |  |   |  |  |  |
|     | □publication of the international application (Rule 12.4(a))        |  |   |  |  |  |
|     |   | international preliminary examination (Rules 55.2(a) and/or 55.2   | B(a))   |  |  |  |
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| 2.  | <b>-</b>  |  |   |  |  |  |
|     | to th   | the receiving Office in response to an invitation under Article 14 are re  | eferred to in this report as "originally filed" and are not |  |  |  |
|     | anne  | nexed to this report):   |   |  |  |  |
|     |   | the international application as originally filed/furnished  |   |  |  |  |
|     |   | the description:   |   |  |  |  |
|     |   | pages  | as originally filed/furnished                               |  |  |  |
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| •   | П   | the claims:  |   |  |  |  |
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|     |   |  | s amended (together with any statement)under Article 19     |  |  |  |
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|     |   | a sequence listing and/or any related table(s) - see Supplemental Box  | Relating to Sequence Listing.                               |  |  |  |
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| 3.  | 3. The amendments have resulted in the cancellation of:             |  |   |  |  |  |
|     | the description, pages  |  |   |  |  |  |
|     | the claims, Nos.  |  |   |  |  |  |
|     | the drawings, sheets/figs   |  |   |  |  |  |
|     |   | the sequence listing (specify):  |   |  |  |  |
|     |   | any table(s) related to sequence listing (specify):  |   |  |  |  |
| 4.  | П   | This report has been established as if (some of) the amendments anne   | exed to this report and listed below had not been made,     |  |  |  |
| 7   | اسا   | since they have been considered to go beyond the disclosure as file  |   |  |  |  |
|     |   | the description, pages   |   |  |  |  |
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|     |   | any table(s) related to sequence listing (specify):  |   |  |  |  |
|     | * <i>If</i>   | If item 4 applies, some or all of those sheets may be marked "supersea   | ed."  |  |  |  |
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International application No. PCT/CN2004/001123

| Box No | o. I   | Basis of the report   |   |  |  |  |
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| 1. W   | ith re   | regard to the language, this report is based on:                      |   |  |  |  |
| . 🗵    |  | the international application in the language in which it was filed   |   |  |  |  |
|        |  | a translation of the international application into                   | , which is the language of a                          |  |  |  |
|        |  | translation furnished for the purposes of:                            |   |  |  |  |
|        |  | international search (Rules 12.3(a) and 23.1(b))                      |   |  |  |  |
|        | publication of the international application (Rule 12.4(a))  |   |   |  |  |  |
|        | international preliminary examination (Rules 55.2(a) and/or 55.3(a))   |   |   |  |  |  |
|        |  |   |   |  |  |  |
| 2. W   | 2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished |   |   |  |  |  |
| to     | to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not |   |   |  |  |  |
| a      | nnex   | exed to this report):   |   |  |  |  |
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| Г      | _  | the description:  |   |  |  |  |
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| 4.     | ] ]  | This report has been established as if (some of) the amendments anner | see indicated in the Supplemental Box (Rule 70.2(c)). |  |  |  |
|        |  | since they have been considered to go beyond the disclosure as filed  |   |  |  |  |
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|        |  | the drawings, sheets/figs   |   |  |  |  |
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|        |  | any table(s) related to sequence listing (specify):                   |   |  |  |  |
| *      | * If item 4 applies, some or all of those sheets may be marked "superseded."   |   |   |  |  |  |

International application No. PCT/CN2004/001070

International application No. PCT/CN2004/001070

#### Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of V:

2.3 Claims 4 relates to the preparation method of the pharmaceuticscontaining the compound of claim 1, while there are no disclosing of same preparation methods in document D1 to D7, thus, the preparation method claimed by claim 4 complies with the criterion of novelty according to the PCT 33(2).

#### 3. Inventive Step

3.1 claim 1 relate to a glucoside from Epimeredi indica(L) Rothmalex of formula I, which are used for the treatment of the disorders relating to estrogen or progestogen dysequilibrium.

Although the compounds disclosed in documents D1-D2, D4-D6 possess high similar stucture with that claimed by claim 1, the compounds disclosed in D1 are used for the treatment of diabetic disorders, the compounds disclosed in D2 are used as cardioactive agent, the compounds disclosed in D4 and D6 are used for the treatment of nerve cell(neurocyte) apoptosis, and there is no detailed disclosing about the medicinal use of compounds in D5. Although document D3 disclosed that the roots of Epimeredi indica(L) Rothmalex can be used for the treatment of the disorders relating to estrogen or progestogen dysequilibrium, but there is no disclosing of detailed compound of formula I. Neither detailed compound of formula I nor the same medicine use are disclosed in document D7.

Thus, in the view of D1 to D7, the compounds claimed by claim 1 complies with the criterion of inventive step according to the PCT 33(3).

3.2 As the compounds claimed by claim 1 complies with the criterion of inventive step, based on the same reason, the composition, formulation, and their praration method of the compounds claimed by claim 1 also complies with the criterion of inventive step according to the PCT 33(3).